(51)

PCT/IL2006/000908

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

AG

PCT

NOTIFICATION CONCERNING TRANSMITTAL OF COPY OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (CHAPTER I OF THE PATENT COOPERATION TREATY)
(PCT Rule 44bis.1(c))

To:

G. E. EHRLICH (1995) LTD.
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RECEIVED
04 FEB 2009
FILE No. 31428
G.E. EHRLICH (1995) LTD.

Date of mailing *(day/month/year)* 22 January 2009 (22.01.2009)	
Applicant's or agent's file reference 31428	**IMPORTANT NOTICE**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL2006/000908	06 August 2006 (06.08.2006)	04 August 2005 (04.08.2005)

Applicant
DUNE MEDICAL DEVICES LTD. et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 31428	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/IL2006/000908	International filing date *(day/month/year)* 06 August 2006 (06.08.2006)	Priority date *(day/month/year)* 04 August 2005 (04.08.2005)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant DUNE MEDICAL DEVICES LTD.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 13 January 2009 (13.01.2009)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Simin Baharlou e-mail: pt09.pct@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
G. E. Ehrlich (1995) Ltd.
11 Menachem Begin Street
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Israel

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	25 SEP 2008

Applicant's or agent's file reference	FOR FURTHER ACTION
31428	See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL 06/00908	06 August 2006 (06.08.2006)	04 August 2005 (04.08.2005)

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61B 17/00 (2006.01)
USPC - 600/202

Applicant DUNE MEDICAL DEVICES LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	19 September 2008 (19.09.2008)	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (April 2007)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL 08/00908

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ on paper

☐ in electronic form

c. time of filing/furnishing

☐ contained in the international application as filed

☐ filed together with the international application in electronic form

☐ furnished subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL 08/00908

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-32, 48-59	YES
	Claims	33-47	NO
Inventive step (IS)	Claims	none	YES
	Claims	1-59	NO
Industrial applicability (IA)	Claims	1-59	YES
	Claims	none	NO

2. Citations and explanations:

Claims 33-47 lack novelty under PCT Article 33(2) as being anticipated by US 2002/0072676 A1 (Afanassieva).

As per claim 33, Afanassieva discloses an element, which defines a surface with a curvature in a first direction, the curvature being at least greater than that of a circle having a diameter of 8cm; and at least two sensors, arranged along the curvature, each defining a viewing angle into a volume, the at least two sensors, sharing a portion of their viewing angles so as to obtain three-dimensional information of the volume (see paras [0045]; [0047]; [0052]; FIG. 3b).

As per claim 34, Afanassieva further discloses the curvature is greater than that of a circle having a diameter of about 6 cm (see FIG. 3b).

As per claim 35, Afanassieva further discloses the curvature is greater than that of a circle having a diameter of about 4 cm (see FIG. 3b).

As per claim 36, Afanassieva further discloses the curvature is greater than that of a circle having a diameter of about 2 cm (see FIG. 3b).

As per claim 37, Afanassieva further discloses the curvature is greater than that of a circle having a diameter of about 1 cm (see FIG. 3b).

As per claim 38, Afanassieva further discloses the curvature is greater than that of a circle having a diameter of about 0.8 cm (see FIG. 3b).

As per claim 39, Afanassieva further discloses the at least two sensors include at least four sensors, arranged as at least two pairs of sensors, each pair being of substantially identical sensors arranged along the curvature, and each pair representing a different type of sensors, for providing three-dimensional information by at least two modalities (see paras [0047]; [0052]).

As per claims 40 and 45-47, Afanassieva discloses a housing, which defines proximal and distal ends, which respect to a tissue, an element, which defines a surface with a curvature in a first direction, the curvature being at least greater than that of a circle having a diameter of 8cm (see FIG. 3b); at least two sensors, arranged along the curvature, each defining a viewing angle into a volume, the at least two sensors sharing a portion of their viewing angles so as to obtain three-dimensional information of the volume; and a signal communication architecture, for providing communication between a signal analyzer and the at least two sensors (see paras [0045]; [0047]; [0052]).

As per claim 41, Afanassieva further discloses insertion to a body lumen (see Abstract).

As per claim 42, Afanassieva further discloses insertion intracorporeally, for minimally invasive procedures (see Abstract).

As per claim 43, Afanassieva further discloses application to subcutaneous tissue, during open surgery (see Abstract).

As per claim 44, Afanassieva further discloses extracorporeal application, wherein the tissue is a skin (see Abstract)

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/IL 06/00908

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:
Box V(2). Citations and Explanations

Claims 1-32 and 48-59 lack an inventive step under PCT Article 33(3) as being obvious over US 2002/0072676 A1 (Afanassieva) in view of US 6,647,089 B1 to Virta et al. (hereinafter 'Virta').

As per claim 1, Afanassieva discloses an element which defines a rigid surface of a linear cross-section, configured to make contact with a tissue (see paras [0001]; [0045]); and at least one sensor, in physical contact with the rigid surface (see Abstract; para [0045]). Afanassieva does not disclose a mechanism, adapted for applying a force to the tissue, the line of force being at as acute angle with the rigid surface, for stretching the tissue against the rigid surface, thus achieving effective contract between the tissue and the rigid surface. Virta discloses a mechanism, adapted for applying a force to the tissue, the line of force being at as acute angle with the rigid surface, for stretching the tissue against the rigid surface, thus achieving effective contract between the tissue and the rigid surface (see Abstract). It would have been obvious to one of ordinary skill in the art to combine the system of Afanassieva with the stretching means of Virta because this decreases the thickness of the skin and provides a more accurate scan.

As per claims 25, 31, and 32, Afanassieva discloses a housing which defines proximal and distal ends, with respect to a tissue; an element, at the proximal end of the probe, the element defining a rigid surface of a linear cross-section, configured to make contact with the tissue (see paras [0001]; [0045]); at least one sensor in physical contact with the rigid surface; and at least one signal communication line, for providing communication between a signal analyzer and the at least one sensor (see Abstract; paras [0001]; [0045]). Afanassieva does not disclose a mechanism, adapted for applying a force to the tissue, the line of force being at an acute angle with the rigid surface, thus achieving effective contact between the tissue and the rigid surface. Virta discloses a mechanism, adapted for applying a force to the tissue, the line of force being at an acute agnle with the rigid surface, thus achieving effective contact between the tissue and the rigid surface (see col. 3, ln. 54-65). It would have been obvious to one of ordinary skill in the art to combine the system of Afanassieva with the stretching means of Virta because this decreases the thickness of the skin and provides a more accurate scan.

As per claims 48, 56, 58, and 59, Afanassieva discloses a structure, formed of a rigid surface configured as a truncated cone (see FIG. 3b), having a first cross-sectional configuration defining an axis (see para [0045]). Afanassieva does not disclose a first mechanism associated with the structure, configured for causing a force to be exerted on a tissue, in a direction, along the axis, at an acute angle a to the rigid surface, for fixing the tissue to the structure, so as to substantially immobilize the tissue; and a second mechanism, associated with the structure, configured for pressing at least one piston sensor against an external surface of the immobilized tissue, thereby exerting a counter force on the immobilized tissue, wherein at least a component of the force is in opposition to at least a component of the counter force, forcing the immobilized tissue against at least one piston sensor, and forcing the at least one piston sensor against the immobilized tissue, bring about an effective contact between the at least one piston sensor and the immobilized tissue. Virta discloses a first mechanism associated with the structure, configured for causing a force to be exerted on a tissue, in a direction, along the axis, at an acute angle a to the rigid surface, for fixing the tissue to the structure, so as to substantially immobilize the tissue; and a second mechanism, associated with the structure, configured for pressing at least one piston sensor against an external surface of the immobilized tissue, thereby exerting a counter force on the immobilized tissue, wherein at least a component of the force is in opposition to at least a component of the counter force, forcing the immobilized tissue against at least one piston sensor, and forcing the at least one piston sensor against the immobilized tissue, bring about an effective contact between the at least one piston sensor and the immobilized tissue (see col. 3, ln. 54-65; FIG. 3b). It would have been obvious to one of ordinary skill in the art to combine the system of Afanassieva with the stretching means of Virta because this decreases the thickness of the skin and provides a more accurate scan.

As per claim 2, Virta further discloses the stretching further includes stretching and pushing (see col. 3, ln. 54-65).

As per claim 3, Afanassieva and Virta do not specifically disclose the acute angle is between 30 degrees and 60 degrees. It would have been obvious to one of ordinary skill in the art to optimize the angle of the force because this provides the stretching without overly compressing the tissue.

As per claim 4, Afanassieva and Virta do not specifically disclose the effective contact is a contact level of at least 95%. It would have been obvious to one of ordinary skill in the art to optimize the contact level because this puts the greatest % of the sensor in contact with the tissue.

As per claim 5, Afanassieva and Virta do not specifically disclose the effective contact is a contact level of at least 99%. It would have been obvious to one of ordinary skill in the art to optimize the contact level because this puts the greatest % of the sensor in contact with the tissue.

As per claim 6, Afanassieva and Virta do not specifically disclose the effective contact is a contact level of at least 99.5%. It would have been obvious to one of ordinary skill in the art to optimize the contact level because this puts the greatest % of the sensor in contact with the tissue.

As per claim 7, Afanassieva and Virta do not specifically disclose the effective contact is a contact level of at least 99.8%. It would have been obvious to one of ordinary skill in the art to optimize the contact level because this puts the greatest % of the sensor in contact with the tissue.

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL 08/00908

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
Box V(2). Citations and Explanations

As per claim 8, Afanassieva further discloses the sensor is an irradiative sensor of a wavelength, and an average distance t1, between the external-most surfaces of the tissue and the sensor, is such that t1 </3 (see Abstract; paras [0012]; [0017]).

As per claim 9, Afanassieva further discloses the sensor is an irradiative sensor of a wavelength, and an average distance t1, between the external-most surfaces of the tissue and the sensor, is such that t1 </10 (see Abstract; paras [0012]; [0017]).

As per claim 10, Afanassieva further discloses the sensor is an irradiative sensor of a wavelength, and an average distance t1, between the external-most surfaces of the tissue and the sensor, is such that t1 </100 (see Abstract; paras [0012]; [0017]).

As per claim 11, Afanassieva further discloses an average distance between external-most surfaces of the tissue and the sensor, is less that 500 Angstroms (see Abstract; paras [0012]; [0017], wherein the sensor is in contact with the tissue).

As per claim 12, Afanassieva further discloses an average distance between external-most surfaces of the tissue and the sensor, is less that 50 Angstroms (see Abstract; paras [0012]; [0017], wherein the sensor is in contact with the tissue).

As per claim 13, Afanassieva further discloses an average distance between external-most surfaces of the tissue and the sensor, is less that 5 Angstroms (see Abstract; paras [0012]; [0017], wherein the sensor is in contact with the tissue).

As per claim 14, Afanassieva the at least one sensor is an irradiative sensor, selected from the group consisting of an optical sensor, an X-Ray sensor, an RF sensor, a MW sensor, an infrared thermography sensor, and an ultrasound sensor (see paras [0012]; [0017]).

As per claim 15, Afanassieva further discloses the at least one sensor is selected from the group consisting of an MR sensor, an impedance sensor, a temperature sensor, a biosensor, a chemical sensor, a radioactive-emission sensor, a nonirradiative RF sensor, and a mechanical sensor (see para [0047]).

As per claim 16, Afanassieva further discloses a plurality of sensors (see paras [0012]; [0017]; [0047]).

As per claim 17, Afanassieva further discloses the at least one sensor includes at least two different types of sensors (see paras [0012]; [0017]; [0047]).

As per claim 18, Afanassieva further discloses the at least one sensor includes at least two different types of sensors, selected from the group consisting of optical sensors, X-ray sensors, RF sensors, MW sensors, infrared thermography sensors, ultrasound sensors, MR sensors, impedance sensors, temperature sensors, biosensors, chemical sensors, radioactive-emission sensors, mechanical sensors, and nonirradiative RF sensors (see paras [0012]; [0017]; [0047]).

As per claim 19, Afanassieva further discloses the element defines a curvature for obtaining three-dimensional information, and further wherein the plurality of sensors includes at least two sensors, arranged along the curvature, each defining a viewing angle, the at least two sensors sharing a portion of their viewing angle, the at least two sensors sharing a portion of their viewing angles so as to obtain three-dimensional information (see paras [0012]; [0017]; [0047]).

As per claim 20, Afanassieva further discloses the plurality of sensors includes at least four sensors, arranged as at least two pairs of sensors, each pair being of substantially identical sensors, and each pair representing a different type of sensor, for providing three-dimensional information by at least two modalities (see paras [0047]; [0052]).

As per claim 21, Virta further discloses the three-dimensional information includes small-scale computerized tomography (see col. 3, ln. 5-18).

As per claims 22 and 26, Afanassieva and Virta do not specifically disclose the mechanism suction. However, Virta discloses suction was well known in the art for drawing tissue into the device (see col. 1, ln. 1, ln. 61-62). therefore, it would have been obvious to one of ordinary skill in the art to utilize suction because this draws in tissue without contact by mechanical means.

As per claim 23, Virta further discloses the mechanism is tweezers-like (see FIG. 2b).

As per claim 24, Virta further discloses the mechanism exerts physical pressure on the tissue (see col. 3, ln. 64-65).

As per claim 27, Afanassieva and Virta do not specifically disclose a pump, which provides the suction, is arranged within the housing. However, pumps were well known in the art for generating the negative pressure associated with suction. Therefore, it would have been obvious to one of ordinary skill in the art to utilize a pump because this allows the generation of the pressure needed for suction.

As per claim 28, Afanassieva and Virta do not specifically disclose the suction is provided by a channel, arranged within the housing and in communication with an external vacuum source. However, vacuums were well known in the art for generating the negative pressure associated with suction. Therefore, it would have been obvious to one of ordinary skill in the art to utilize a channel and a vacuum source because this allows the generation of the pressure needed for suction without additional machinery within the housing.

As per claim 29, Afanassieva and Virta do not specifically disclose the channel is further operative to drain off tissue fluids. It would have been obvious to one of ordinary skill in the art to utilize a drain because this prevents bodily fluids from impeding an accurate reading.

----------Please See Continuation Sheet----------

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL 08/00808

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:
Box V(2). Citations and Explanations

As per claims 30 and 57, Virta further discloses configured for an application, selected from the group consisting of extracoporeal application to a skin, intracoporeal insertion thought a body lumen, intracoporeal insertion for a minimally invasive procedure, and application to subcutaneous tissue, during open surgery (see Abstract; FIG. 2B).

As per claim 49, Virta further discloses the at least one piston sensor includes at least two piston sensors of a same type (see col. 3, ln. 32 -44).

As per claim 50, Virta further discloses the at least one piston sensor includes at least two piston sensors of different type (see col. 3, ln. 32-44).

As per claim 51, Afanassieva further discloses at least one cone sensor arranged on the rigid surface (see FIG. 3b).

As per claim 52, Afanassieva further discloses at least two cone sensors, arranged on the rigid surface of the linear cross section (See paras [0047]; [0045]).

As per claim 53, Afanassieva further discloses the at least two cone sensors are arranged along the curvature, each cone sensor defining a viewing angle, the at least two cone sensors sharing a portion of the viewing angles so as to obtain three-dimensional information (see paras [0045]; [0047]).

As per claim 54, Afanassieva further discloses the at least one cone sensor includes at least four cone sensors, arranged as at least two pairs of cone sensors, each pair being of substantially identical cone sensors, and each pair representing a different type of cone sensors, for providing three-dimensional information by at leat two modalities (see paras [0045]; [0047]; [0052]).

As per claim 55, Afanassieva and Virta do not specifically disclose the first mechanism is a suction source, for fixing and substantially immobilizing the tissue, by suction. However, Virta discloses suction was well known in the art for drawing tissue into the device (see col. 1, ln. 1, ln. 61-62). therefore, it would have been obvious to one of ordinary skill in the art to utilize suction because this draws in tissue without contact by mechanical means.

Claims 1-59 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.